REMARKS

Claims 16-27 are pending. Paragraph [0164] of the specification on page 52 has been amended to recite the generic names for CARBOPOL 934 NF and METHOCEL E4M as polyacrylic polymer and hydroxypropylmethylcellulose, respectively. At the time the present application was filed (August 22, 2001), one of ordinary skill in the art knew that CARBOPOL 934 NF and METHOCEL E4M referred to a polyacrylic polymer and a hydroxypropylmethylcellulose, respectively. See, for example, the enclosed commercial Material Safety Data Sheet dated November 2001 that identifies CARBOPOL 934 NF as an acrylic polymer; and Example 1 of U.S. Patent 6,713,081 filed March 2001 that identifies METHOCEL E4M as hydroxypropylmethylcellulose. Claims 26 and 27 have been amended. Support for the recitation of a polyacrylic polymer and a hydroxypropylmethylcellulose in these claims are found throughout the specification, for example, page 3, lines 19 and 23. No new matter is added.

Claims 26 and 27 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for reciting trade names. Applicants have amended the claims to recite the respective generic names. Thus, the claims are now definite and are in full compliance with the requirements of 35 U.S.C. § 112, second paragraph.

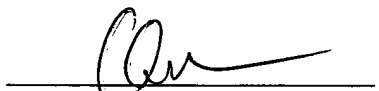
Claims 16-24 stand rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by U.S. Patent No. 5,877,309 (hereinafter the "309 patent"). Applicants respectfully disagree and assert that the 309 patent cannot anticipate claims 16-24 because the 309 patent does not teach or suggest all the elements of claims. For example, claims 16-24 recite the elements of "a first population of carrier particles comprising said drug and a bioadhesive compound" and a "second population of carrier particles comprising a penetration enhancer." The 309 patent does not teach or suggest a formulation comprising "a first population" and a "second population". Although the 309 patent reports a formulation comprising a polyacrylate (a bioadhesive) (col. 23, ln. 39) and a capric acid (a penetration enhancer) (col. 22, ln. 17), the 309 patent fails to teach that the polyacrylate is part of "a first population of carrier particles comprising a drug and a bioadhesive compound", and that the capric acid is part of "a second

population of carrier particles". Since the 309 patent does not teach all the elements of claims 16-24, the 309 patent cannot anticipate these claims.

Claims 16, 21 and 25 stand rejected under 35 U.S.C. § 103 (a) for allegedly being obvious over U.S. Patent No. 5,877,309 in view of U.S. Patent No. 5,514,788 (hereinafter the "788 patent"). Applicants respectfully disagree and assert that the Office Action has not established a prima facie case of obviousness. For example, the Office Action has not established that the cited references teach all the elements of the rejected claims. Similar to claims 16 and 21, claim 25 recites the elements of "a first population of carrier particles comprising said drug and a bioadhesive compound" and a "second population of carrier particles comprising a penetration enhancer." As discussed above, the 309 patent does not teach "a first population of carrier particles" and "a second population of carrier particles". The 788 patent does not cure this deficiency, as it also fails to teach these limitations. Thus, claims 16, 21 and 25 are not rendered obvious by the cited art because neither the 309 patent nor the combination of the 309 patent and the 788 patent teach all the elements of the claims.

In view of the foregoing, Applicants submit that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



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Registration No. 46,957

Date: April 29, 2004

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Enclosures:

Doc No. 2054225

MATERIAL SAFETY DATA SHEET

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1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	CARBOPOL* 934NF Polymer
Company Identification	Noveon, Inc. 9911 Brecksville Rd. Cleveland, OH 44141-3247 United States of America
Telephone	(800) 331-1144 / (216) 447-5000
Chemtrec (24 Hour)	(800) 424-9300
Preparer	Health, Safety, and Environmental Department
Product Description	Acrylic polymer for thickening.

2. COMPOSITION, INFORMATION ON INGREDIENTS

--Ingredient--	-CAS Number-	---%---
Acrylic polymer	0009003-01-4	<100

Notes:
Amounts specified are typical and do not represent a specification.

3. HAZARDS IDENTIFICATION

Acute Health Effects
Powder/dust eye irritation is a physical, not a chemical effect.
Solid particles on the eye (powder/dust) may cause pain and be accompanied by irritation.
Dust inhalation may cause coughing, mucous production and shortness of breath.
Chronic Health Effects
Contact dermatitis may occur in individuals under extreme conditions of prolonged and repeated contact, high exposure and temperature, and occlusion (held onto the skin) by clothing.
Routes of Exposure/Entry
Eyes, skin contact, inhalation, ingestion.
Target Organs
Respiratory system, skin.
Medical Conditions Aggravated by Exposure
Pre-existing skin problems may be aggravated by prolonged or repeated contact.
Pre-existing respiratory disease(s) may be aggravated by prolonged or repeated inhalation of airborne dust.

Carcinogenic Status
The components of this mixture are not known to be listed or regulated by IARC, NTP, OSHA or ACGIH.
Not listed or regulated by IARC, NTP, OSHA, or ACGIH.

4. FIRST AID MEASURES

If irritation or other symptoms (as noted above) occur or persist from any route of exposure, remove the affected individual from the area: see a physician/get medical attention.

Eye Contact
Water (moisture) swells this product into a gelatinous film and, when in contact with the eye, may be difficult to remove using only water. Immediately flush eyes with plenty of one percent (1%) physiological saline for five minutes while holding eyelids open; see a physician. If no saline is easily available, flush eyes with plenty of clean water for 15 minutes; see a physician.

Skin Contact
Wash the affected area thoroughly with plenty of water and soap.

Inhalation
If any processing vapors, decomposition products or particulates are inhaled, remove individual(s) to fresh air. Provide protection before allowing reentry.

Ingestion
No ingestion effects known. Treat symptomatically.

5. FIRE FIGHTING MEASURES

NFPA Flammability Class	N/A
Flash Range	Not Applicable
Explosive Range	See information below.

Fire and Explosive Properties
Typical results expected for this family of products:

Minimum explosive concentration:	0.13 oz/ft3 (130 g/m3)
Minimum ignition energy:	1.60 joules (dispersed dust cloud)
Deflagration Index, Kst (estimate):	130 bar m/sec
Volume resistivity:	3.24 x 10+16 ohm-cm
Maximum rate of pressure rise:	5,500 psi @ 0.5 oz/ft3 (380 bars @ 500 g/cm3)
Maximum explosion pressure:	70 psi @ 0.5 oz/ft3 (4.8 bars @ 500 g/cm3)
Ignition temperature of dust cloud:	968 F (520 C)
National Electrical Code (NFPA 70):	Group G dust.

As with all organic dusts, fine particles suspended in air in critical proportions and in the presence of an ignition source may ignite and/or explode. Dust may be sensitive to ignition by electrostatic discharge, electrical arcs, sparks, welding torches,

cigarettes, open flame, or other significant heat sources. As a precaution, implement standard safety measures for handling finely divided organic powders. See Section 7 for suggested measures. This product has a high volume resistivity and a propensity to build up static electricity which may be discharged as a spark. A spark can be an ignition source for solvent vapor/air mixtures. If you add this product to a solvent, ensure appropriate safe handling practices such as provision for inerting flammable vapors and measures such as those cited above.

Extinguishing Media

Use water spray, dry chemical, or foam. Carbon dioxide may be ineffective on larger fires due to a lack of cooling capacity which may result in reignition.

Fire Fighting Instructions

Avoid hose streams or any method which will create dust clouds. Wear self-contained breathing apparatus (SCBA) equipped with a full facepiece and operated in a pressure-demand mode (or other positive pressure mode) and approved protective clothing. Personnel without suitable respiratory protection must leave the area to prevent significant exposure to hazardous gases from combustion, burning or decomposition. In an enclosed or poorly ventilated area, wear SCBA during cleanup immediately after a fire as well as during the attack phase of firefighting operations.

6. ACCIDENTAL RELEASE MEASURES

Containment Techniques

Using care to avoid dust generation, vacuum or sweep into a closed container for reuse or disposal. Do not sweep or flush spilled product into public sewer, streams or other water systems.

Clean-Up Techniques

If inhalation of dust cannot be avoided, wear a particulate respirator approved by NIOSH/MSHA.

CAUTION: Contact with water creates a very slippery film. If this occurs, the film can be broken down for cleanup with detergent solution.

7. HANDLING AND STORAGE

Handling

Although the risk of a dust explosion is low, as a precaution, implement the following safety measures:

Bond, ground and properly vent conveyors, dust control devices and other transfer equipment.

Eliminate ignition sources (e.g., sparks, static buildup, excessive heat, etc.).

Prohibit flow of polymer, powder or dust through non-conductive ducts, vacuum hoses or pipes, etc.; only use grounded, electrically conductive transfer lines when pneumatically conveying product.

Prevent accumulation of dust (e.g., well-ventilated conditions, promptly vacuuming spills, cleaning overhead horizontal surfaces, etc.).
Use under well-ventilated conditions.
Do not get in eyes.
Do not ingest, taste, or swallow.
Avoid repeated or prolonged skin contact.
Avoid routine inhalation of dust of any kind. Exercise care when emptying containers, sweeping, mixing or doing other tasks which can create dust.
Wash thoroughly after handling this product. Always wash up before eating, smoking or using the facilities.

Storage

Keep container closed when not in use.
Store in dry area.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

	--ACGIH-TWA---	-ACGIH-STEL---	---OSHA-TWA---	--OSHA-STEL---
Acrylic polymer	N/E	N/E	N/E	N/E

Notes:

Noveon recommends an 8-hour TWA exposure limit of 0.05 mg/m3 for the polymer in this product.

Engineering Controls

Ventilation guidelines/techniques may be found in publications such as Industrial Ventilation: American Conference of Governmental Industrial Hygienists, 1330 Kemper Meadow Drive, Cincinnati, OH, 45240-1634, USA.
Ventilation must be adequate to maintain the ambient workplace atmosphere below the exposure limit(s) outlined in the MSDS.
Always provide effective general and, when necessary, local exhaust ventilation to draw dust away from workers to prevent routine inhalation.

Eye/Face Protection

Eye protection (e.g., goggles) suitable for keeping dust out of the eyes.

Skin Protection

Wear protective gloves.

Respiratory Protection

If respirable dust exposures exceed 0.05 mg/m3 (8-hour TWA), wear a NIOSH-approved respirator equipped with high efficiency particulate (HEPA) filters.
Use respirator in accordance with manufacturer's use limitations and OSHA standard 1910.134 (29CFR).

9. PHYSICAL AND CHEMICAL PROPERTIES

Form	Powder
Appearance/Color	White
Odor	Slight acetic
Solubility (in water)	Appreciable
pH Value	2.5-3.0 @ 1% in H20
Boiling Range	Not Applicable
Vapor Pressure (mmHg)	Not Applicable
Melting Point	Not Available
Evaporation Rate	Not Volatile
Vapor Density	Not Volatile
Partition Coefficient	Not Available
% Volatile Weight	(moisture) < 2.%
Specific Gravity	~ 1.40
Bulk Density	0.19-0.24 g/mL

10. STABILITY AND REACTIVITY

Stability	This product is stable
Hazardous Polymerization	Hazardous polymerization will not occur

Incompatibility with other materials
Heat may be generated if polymer comes in contact with strong basic materials such as ammonia, sodium hydroxide, potassium hydroxide or strongly basic amines. Precautions beyond those described herein, such as chemical splash goggles or protective clothing, must be considered as the need exists.

Hazardous Decomposition Products
Carbon monoxide, carbon dioxide, hydrocarbons, and irritating vapors.

11. TOXICOLOGICAL INFORMATION

Route	Species	Exposure and Dose
Acrylic polymer		
Oral	Rat, adult	LD50 > 2500. mg/kg
Skin	Rabbit, adult	LD50 > 3000. mg/kg

Note: These results are typical for this family of polymers.
Chronic oral toxicity: No significant effects in rats or dogs fed with resin as 5% of diet for 6-1/2 months.
Skin: No evidence of irritation or sensitization during human patch testing.

No evidence of adverse lung effects from polyacrylate dust exposure was observed in studies of workers. Neither lower airway symptoms, chronic parenchymal disease, radiographic changes, nor clinically important effects on lung function were found to result from polyacrylate exposure. Only a small increase in upper respiratory

symptoms appeared to be related to exposure. However, various lung effects such as inflammation, hyperplasia (abnormal increases in the number of cells composing a tissue or organ), scarring (fibrosis), changes in the air sac (alveolar) ducts of the lung, and tumors were noted in laboratory studies with rodents inhaling concentrations of a water absorbent sodium polyacrylate dust greater than 0.05 mg/m3 for the majority of their lives. Furthermore, some lung or lung cell effects were found in rodent laboratory studies of shorter duration.

12. ECOLOGICAL INFORMATION

Acrylic polymer
96 Hour static acute toxicity: Bluegill, Sunfish, LC50 580-2000 mg/L
96 Hour static acute toxicity: Daphnia Magna, LC50 168-280 mg/L
Crosslinked polyacrylic acid polymers in this product are not biodegradable; do not inhibit waste treatment bacteria; and do not pass through typical wastewater treatment to the environment, but are instead removed with the biomass.

13. DISPOSAL CONSIDERATIONS

For waste disposal purposes, this product is not known to be defined or designated as hazardous by current provisions of the Federal (EPA) Resource Conservation and Recovery Act (RCRA, 40CFR261).
Incinerate or landfill waste in a properly permitted facility in accordance with federal, state and local regulations.
In appropriate dust/air ratio, dust cloud in air has explosion potential. Therefore, land disposal must be in closed containers.
If disposal is in bulk form, recognize that this polymer absorbs moisture resulting in a gelatinous mass that is unable to support human weight.

14. TRANSPORTATION INFORMATION

UN Number	N/A
UN Pack Group	N/A
UN Class	N/A
ICAO/IATA Class	N/A
IMDG Class	N/A
ADR/RID Class	N/A

Notes:
This product is NOT REGULATED for domestic and international transportation.

15. REGULATORY INFORMATION

--SARA Title III Section 313----------

This product does not contain any substance(s) subject to the reporting requirements (i.e., at or above de minimus quantities) of Section 313 of Title III of the Superfund Amendments and Reauthorization Act (SARA) 40 CFR 372.

--SARA Title III Section 312 Hazard Category (40 CFR 311/312)--

Acute Health:	No	Release of Pressure:	No
Chronic Health:	Yes	Reactive:	No
Fire:	No		

--California Proposition 65------

"Substances known to the state of California to cause cancer, birth defects or other reproductive harm": None known to be present or none in reportable amounts for occupational exposure as per OSHA's approval of the California Hazard Communication Standard, Federal Register, page 31159 ff, 6 June 1997.

US (Federal) Regulations

TSCA: All components of this product are either listed on the U.S. Toxic Substances Control Act (TSCA) inventory of chemicals or are otherwise compliant with TSCA regulations.

International Regulations

Canadian DSL: All components in this product are on the Canadian Domestic Substances List (DSL) or are exempt from listing.
Canadian Ingredient Disclosure List (WHMIS): Not applicable.
Canadian WHMIS: This product is NOT controlled under the Canadian Workplace Hazardous Materials Information System (WHMIS).
Monomers are listed: European Union EINECS.

16. OTHER INFORMATION

HMIS Rating (H-F-R-PPI) 0-1-0-B
NFPA Rating (H-F-R) 2-1-0
KEY: 0=Insignificant; 1=Slight; 2=Moderate; 3=High; 4=Extreme.
Hazardous Materials Identification System (HMIS), National Paint and Coatings Assn. rating applies to product "as packaged" (i.e., ambient temperature).
National Fire Protection Association (NFPA) rating identifies the severity of hazards of material during a fire emergency (i.e., "on fire").

Legend:

*:	A Trademark of Noveon, Inc.
ACGIH:	American Conference of Governmental Industrial Hygienists
A1:	Confirmed human carcinogen
A2:	Suspected human carcinogen
A3:	Animal carcinogen

CAS No: Chemical Abstract Service Registry Number
IARC: International Agency for Research on Cancer
Group1: Carcinogenic to humans
Group2A: Probably carcinogenic to humans
Group2B: Possibly carcinogenic to humans
Group3: Unclassifiable as a carcinogen to humans
MSHA: Mine Safety and Health Administration
NIOSH: National Institute for Occupational Safety and Health
NTP: National Toxicology Program
N/A: Not Applicable
N/E: None Established
OSHA: Occupational Safety and Health Administration
PEL: Permissible Exposure Limit
PNOC: Particulates Not Otherwise Classified
RTK: Right To Know
STEL: Short Term Exposure Limit (15 minute Time Weighted Average)
TLV: Threshold Limit Value
C: Ceiling limit
S: Skin notation refers to the potential significant contribution to the overall exposure by the cutaneous route including mucous membranes and the eyes and by direct skin contact with the substance
WEEL: Workplace Environmental Exposure Level
WHMIS: Canadian Workplace Hazardous Materials Information System

Users Responsibility/Disclaimer of Liability

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